JAN 1 2 2001

K003226

Section 12: Premarket Notification 510(k) Summary

1. *Submitter's Name / Contact Person*

Carolyn Anderson
Regulatory Specialist
Lifecore Biomedical, Inc.
Ph: 952-368-6324

Date Submission Prepared: October 11, 2000

2. *General Information*

Trade Name	The Lifecore Stage-1 Single Stage RBM Dental Implant System consists of the following products: • Single Stage Implant, RBM, 4.1mm, 1.8mm Collar (RDS) • Single Stage Implant, RBM, 4.1mm, 2.8mm Collar (RDS) • Single Stage Implant, RBM, 4.8mm, 1.8mm Collar (RDS) • Single Stage Implant, RBM, 4.8mm, 2.8mm Collar (RDS) • Single Stage Implant, RBM, 4.8mm × 6.5mm Flare, 1.8mm Collar (WDS) • Single Stage Implant, RBM, 4.8mm × 6.5mm Flare, 2.8mm Collar (WDS) • Indexed Abutment System (RDS only) • COC Abutment System (RDS & WDS) • O-Ring Abutment System (RDS only) • Laboratory and restorative components • Surgical drills and taps
Common / Usual Name	Dental Implant
Classification Name	Endosseous Implant (21CFR 872.3640)
Identification of Equivalent Devices	▪ Lifecore Stage-1™ Single Stage Regular Diameter TPS Dental Implant System (K991114, K994205), manufactured by Lifecore Biomedical, Inc. ▪ ITI 4.1mm Solid Screw and Wide Neck Implants and Accessories (K894595, K920768, K955281), manufactured by Straumann Dental ▪ SwissPlus Internal Octagon Implant, manufactured by Paragon Implant Company (510(k) number unknown).

3. *Device Description*

The Stage-1™ Single Stage RBM Dental Implant System consists of single-stage, root-form dental implants, associated abutment systems, which provide the clinician with cement-retained, screw-retained and overdenture-type restorative options. The system also includes surgical and restorative instrumentation: twist drills, surgical taps, surgical depth probe, depth gauges, abutment drivers, latch-type drivers, open end wrench and handpiece adapters. The implants are packaged with a cover screw and placement head. Prosthetics and surgical tools are each

packaged separately to allow the clinician to choose only those components required for each clinical situation. The portion of the implant which is embedded in bone is subjected to a proprietary surface treatment consisting of blasting with calcium phosphate resorbable blast media and subsequent acid passivation to yield a roughened titanium surface. The non-submerged portion is machined smooth to allow for the attachment of epithelial tissue. This surgical procedure eliminates the need for the second (uncovery) surgery that is required in two-stage implant systems.

4. Intended Use

Lifecore's Stage-1 Single Stage RBM Dental Implant system is intended for use in either partially or fully edentulous mandibles and maxillae in the following areas:

- Support of fixed (cement retained) restorations utilizing abutment options.
- Support of fixed detachable (screw retained) prosthetics utilizing multiple abutment options.
- Overdenture retention by means of an o-ring or bar appliance.
- Terminal or intermediate abutment support for fixed bridgework.
- Free standing restorations without involvement of adjacent dentition when the locking taper is engaged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2001

Ms. Carolyn Anderson
Regulatory Specialist
Lifecore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318

Re: K003226
Trade Name: Lifecore Stage-1 Single Stage RBM Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: October 11, 2000
Received: October 16, 2000

Dear Ms. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment G: Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003226

Device Name:
Lifecore Stage-1 Single Stage RBM Dental Implant System:

Indications For Use:
The Indications for Use Statement is provided in Attachment D.

Lifecore's Stage-1 Single Stage RBM Dental Implant system is intended for use in either partially or fully edentulous mandibles and maxillae in the following areas:

- Support of fixed (cement retained) restorations utilizing abutment options.
- Support of fixed detachable (screw retained) prosthetics utilizing multiple abutment options.
- Overdenture retention by means of an o-ring or bar appliance.
- Terminal or intermediate abutment support for fixed bridgework.
- Free standing restorations without involvement of adjacent dentition when the locking taper is engaged.

Note: The Stage-1 Single Stage RBM Dental Implant System is not intended for immediate load procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003226